Supreme Court, U.S.
FILED
041251 MAR 17 2005
OFFICE OF THE CLERK

No.

IN THE

Supreme Court of the United States

MEDPOINTE HEALTHCARE INC.,

Petitioner,

v.

HI-TECH PHARMACAL CO., INC.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

ERIC B. WOLFF
Counsel of Record
GREGORY F. CORBETT
STEVEN A. ENGEL
KIRKLAND & ELLIS LLP
655 Fifteenth Street, N.W.
Washington, D.C. 20005

Counsel for Petitioner

March 17, 2005

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

QUESTIONS PRESENTED

1. Whether the Federal Circuit's modification of the preliminary injunction standard to require a patentee seeking a preliminary injunction to demonstrate a "clear case" of patent validity is inconsistent with federal law, which requires a presumption of patent validity, 35 U.S.C. § 282, and inconsistent with the traditional equitable standards governing the grant of preliminary injunctive relief, which require only some likelihood of success on the merits combined with a showing of irreparable harm.

2. Whether the Federal Circuit's application of the "clear case" of patent validity requirement to review only whether a patentee has demonstrated the heightened showing on the merits is improper because it is inconsistent with the traditional purposes of preliminary injunctions to protect the status quo and prevent irreparable harm, as reflected in the balancing analyses applied by this Court and other circuits.

CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rule 29.6, petitioner MedPointe Healthcare Inc. states that its parent corporations and publicly held companies that hold 10 percent or more of its stock are MedPointe Inc. and The CPI Development Corporation.

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED i

CORPORATE DISCLOSURE STATEMENT ii

TABLE OF AUTHORITIES v

INTRODUCTION 1

OPINIONS BELOW 3

JURISDICTION 3

PERTINENT STATUTORY PROVISIONS 4

STATEMENT OF THE CASE 4

REASONS FOR GRANTING THE WRIT 8

I. THE FEDERAL CIRCUIT ERRED BY RAISING THE BAR ON PATENTEES SEEKING TO OBTAIN A PRELIMINARY INJUNCTION 8

A. The Federal Circuit's Preliminary Injunction Requirement Of A "Clear Case" Supporting Patent Validity Is Contrary to Law 9

B. The Injunction Granted By The District Court Satisfied Traditional Equitable Standards 10

C. The Federal Circuit's Aggressive Application Of The "Clear Case" Of Patent Validity Requirement Was The Basis For Vacating The Preliminary Injunction 12

II. REVIEWING PRELIMINARY INJUNCTIONS SOLELY FOCUSING UPON A HEIGHTENED STANDARD ON THE MERITS IS INCONSISTENT WITH THIS COURT'S PRECEDENT AND THE APPROACHES OF OTHER CIRCUITS 12

TABLE OF CONTENTS (Cont.)

Page

A. The Circuits Apply Conflicting Preliminary Injunction Standards 13

B. The Federal Circuit's Fixation Upon Whether A "Clear Case" Of Validity Has Been Shown Is Improper 16

CONCLUSION 17

TABLE OF AUTHORITIES

Page(s)

Cases

Abbott Labs. v. Mead Johnson & Co.,
971 F.2d 6 (7th Cir. 1992).....14

Al-Fayed v. CIA,
254 F.3d 300 (D.C. Cir. 2001).....15

Amazon.Com, Inc. v. BarnesAndNoble.Com, Inc.,
239 F.3d 1343 (Fed. Cir. 2001).....1, 9, 16

Amoco Prod. Co. v. Village of Gambell,
480 U.S. 531 (1987).....2, 10

California v. Am. Stores Co.,
495 U.S. 271 (1990).....13

Cardinal Chemical Co. v. Morton International Inc.,
508 U.S. 83 (1993).....8, 16

Ciena Corp. v. Jarrard,
203 F.3d 312 (4th Cir. 2000).....14

County Sec. Agency v. Ohio Dep't of Commerce,
296 F.3d 477 (6th Cir. 2002).....15

Déjà Vu of Nashville, Inc. v. Metro. Gov't of Nashville & Davidson County,
274 F.3d 377 (6th Cir. 2001).....14

Dennison Mfg. Co. v. Panduit Corp.,
475 U.S. 809 (1986).....10

Entergy, Ark., Inc. v. Nebraska,
210 F.3d 887 (8th Cir. 2000).....15

TABLE OF AUTHORITIES (Cont.)

Page(s)

Horton v. City of St. Augustine,
272 F.3d 1318 (11th Cir. 2001).....15

Irwin v. Dixion,
50 U.S. 10 (1850).....13

Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc.,
596 F.2d 70 (2d Cir. 1979).....15

Kikumura v. Hurley,
242 F.3d 950 (10th Cir. 2001).....15

Palmer v. Braun,
287 F.3d 1325 (11th Cir. 2002).....15

Polymer Tech., Inc. v. Bridwell,
103 F.3d 970 (Fed. Cir. 1996).....11

Prairie Band of Potawatomi Indians v. Pierce,
253 F.3d 1234 (10th Cir. 2001).....14

Safety-Kleen, Inc. v. Wyche,
274 F.3d 846 (4th Cir. 2001).....15

Sammartano v. First Judicial District Court,
303 F.3d 959 (9th Cir. 2002).....16

Serono Labs., Inc. v. Shalala,
158 F.3d 1313 (D.C. Cir. 1998).....14

United Indus. Corp. v. Clorox Co.,
140 F.3d 1175 (8th Cir. 1998).....14

TABLE OF AUTHORITIES (Cont.)

Page(s)

University of Texas v. Camenisch,
451 U.S. 390 (1981) 4, 13

Walgreen Co. v. Hood,
275 F.3d 475 (5th Cir. 2001) 15

Weinberger v. Romero-Barcelo,
456 U.S. 305 (1982) 2, 10

Yakus v. United States,
321 U.S. 414 (1944) 13

Statutes & Regulations

28 U.S.C. § 1254(1) 3

35 U.S.C. § 282 ..... 1, 4, 9

35 U.S.C. § 283 ..... 1, 4

Other Authorities

11A Charles Alan Wright, *et al.*,
Federal Practice & Procedure (2d ed. 1995) 13

Audin, Linz, *On Posner, and Newton, and Twenty-First Century Law: An Economic and Statistical Analysis of the Posner Rule for Granting Preliminary Injunctions*,
23 Loy. L.A. L. Rev. 1215 (1990) 3

TABLE OF AUTHORITIES (Cont.)

Page(s)

Denlow, Morton, *The Motion for a Preliminary Injunction: - Time for a Uniform Federal Standard*, 22 Rev. Litig. 495 (2003).....3, 13

Landis, James, Note, *Amazon.Com: a Look at Patenting Computer Implemented Business Methods Following State Street*, 2 N.C.J.L. & Tech. 1 (2001) 9

Lee, Thomas R., *Preliminary Injunctions and the Status Quo*, 58 Wash. & Lee L. Rev. 109 (2001).....14

Leubsdorf, John, *The Standard for Preliminary Injunctions*, 91 Harv. L. Rev. 525 (1978) 3, 13

Vaughn, Lea B., *A Need for Clarity: Toward a New Standard for Preliminary Injunctions*, 68 Or. L. Rev. 839 (1989).....3

Wolf, Arthur D., *Preliminary Injunctions: The Varying Standards*, 7 W. New Eng. L. Rev. 173 (1984) 3

INTRODUCTION

This petition arises from a doctrine in the Federal Circuit—the circuit court with exclusive jurisdiction over patent appeals—that imposes a higher standard on patent holders seeking preliminary injunctive relief than on other litigants. For the past several years, the Federal Circuit has imposed upon patent holders seeking a preliminary injunction a threshold requirement that the patentee demonstrate a "clear case supporting the validity of the patent in suit." *See, e.g., Amazon.Com, Inc. v. BarnesAndNoble.Com, Inc.*, 239 F.3d 1343, 1359 (Fed. Cir. 2001). When reviewing preliminary injunctions, if the Federal Circuit decides that a "clear case" has not been demonstrated, that is the end of the inquiry. The preliminary injunction is vacated without considering irreparable harm, balancing the equities, or weighing the value of maintaining the *status quo*.

The Federal Circuit's modification of the preliminary injunction standard in patent cases is inconsistent with federal patent law and inconsistent with the basis for preliminary injunctive relief in the first place, as reflected by this Court's precedent and the preliminary injunction standards of other circuits.

Congress has expressly provided preliminary injunctive relief for patentees, 35 U.S.C. § 283, and mandated a presumption that patents are valid, *id.* § 282. A requirement that patentees must demonstrate a "clear case" of patent validity is essentially a judicially created presumption against the presumption of validity established by Congress. It is also a modification of the traditional standard that a party seeking a preliminary injunction need only show some likelihood of success on the merits along with irreparable injury. A "clear case" on the merits is not required.

Since establishing the "clear case" requirement, the Federal Circuit's practice has been to transform the

deferential review of a preliminary injunction into a *de novo* review of the validity of an issued patent without consideration of other preliminary injunction factors. In the decision below, the district court conducted a three-day evidentiary hearing and issued a 94-page opinion weighing all the factors before granting the preliminary injunction. A divided court of appeals cast aside those findings and entered new findings based on the Federal Circuit's higher standard and a non-deferential review of the merits.

In determining whether to grant a preliminary injunction, courts traditionally consider, in one way or another, (1) whether the plaintiff has an adequate remedy at law, (2) whether the plaintiff will suffer irreparable harm without an injunction, (3) a balancing of the plaintiff's and defendant's harm, (4) whether the plaintiff has a reasonable likelihood of success on the merits, (5) how the injunction will affect the public interest, and (6) the preservation of the *status quo* pending trial on the merits. That balancing analysis follows directly from the fact that "[t]he Court has repeatedly held that the basis for injunctive relief in the federal courts has always been irreparable injury and the inadequacy of legal remedies." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311 (1982); *see also Amoco Prod. Co. v. Village of Gambell*, 480 U.S. 531, 542 (1987). Moreover, a preliminary injunction (and appellate review of a preliminary injunction) is not a procedural substitute for trial (and an appeal) on the merits.

The Federal Circuit's treatment of appellate review of preliminary injunctions conflicts with the purpose of preliminary injunctions and the various balancing analyses used by most circuits. This case is an ideal vehicle to clarify what is and is not proper preliminary injunction procedure, if by nothing else, definitively holding that the Federal Circuit's narrow focus upon the merits, and its requirement of a heightened showing on the merits, are improper. That holding alone would be welcome, as the federal judiciary has

developed a "'dizzying' array of standards" for preliminary injunctions. *See* Hon. Morton Denlow, *The Motion for a Preliminary Injunction: Time for a Uniform Federal Standard*, 22 Rev. Litig. 495, 497 (2003) (quoting John Leubsdorf, *The Standard for Preliminary Injunctions*, 91 Harv. L. Rev. 525, 526 (1978)). Voluminous secondary literature cries out for some clarification from this Court.[1]

OPINIONS BELOW

The Federal Circuit's decision is reported at 115 Fed. Appx. 76 and reprinted in the Appendix ("App.") at 1a-11a. The decision of the United States District Court for the District of New Jersey is reprinted in the Appendix at 13a-89a.

JURISDICTION

The Federal Circuit rendered its decision on November 17, 2004, App. 1a-11a, and denied a timely petition for rehearing on December 17, 2004, App. 12a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

---

[1] *See, e.g.*, Lea B. Vaughn, *A Need for Clarity: Toward a New Standard for Preliminary Injunctions*, 68 Or. L. Rev. 839 (1989); *see also* Linz Audain, *On Posner, and Newton, and Twenty-First Century Law: An Economic and Statistical Analysis of the Posner Rule for Granting Preliminary Injunctions*, 23 Loy. L.A. L. Rev. 1215, 1222 (1990) (observing that "the federal courts use two, three, four and five-step standards without any apparent logic to their choice" and that "even their 'four-part' standards differ from each other"); Wolf, Arthur D., *Preliminary Injunctions: The Varying Standards*, 7 W. New Eng. L. Rev. 173, 184 (1984) (disparaging the "widespread disagreement among the courts of appeals regarding the applicable criteria").

PERTINENT STATUTORY PROVISIONS

35 U.S.C. § 282 provides in relevant part:

"A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim."

35 U.S.C. § 283 provides in relevant part:

"The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable."

STATEMENT OF THE CASE

At issue in this case is whether it is consistent with federal law for the Federal Circuit to require patentees seeking a preliminary injunction in patent infringement cases to demonstrate a "clear case" of patent validity, and whether the Federal Circuit errs in limiting its review of preliminary injunctions to the narrow merits issue of whether a "clear case" of patent validity was shown, when the general purposes for granting a preliminary injunction are (1) maintaining the *status quo*, (2) preserving the court's ability to render a meaningful decision, and (3) minimizing the risk of error. *See University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981).

A. General Background

Petitioner MedPointe is a small pharmaceutical company that researches, develops, and markets various branded prescription drugs, including those in the areas of

cough/cold, allergy and respiratory, and pain management. Respondent Hi-Tech is a generic pharmaceutical company that does not develop new drugs but rather sells generic versions of innovator drugs already on the market.

In the spring of 2000, Alexander D'Addio, currently MedPointe's Vice President of Product and Process Development, conceived of a new cough/cold product containing the drugs carbetapentane tannate, phenylephrine tannate and pyrilamine tannate. App. 18a. Carbetapentane tannate is an antitussive (anti-cough), pyrilamine tannate is an antihistamine, and phenylephrine tannate is a decongestant.

The tannate salts of these active ingredients were known to be difficult to work with, and nobody had previously combined these three ingredients in a single product. In Dr. D'Addio's nineteen years of pharmaceutical experience, he deemed these products the hardest to formulate because of their high tannate levels. App. 65a-66a. MedPointe invested approximately $3 million into researching and developing this drug combination. App. 88a.

On January 26, 2001, Dr. D'Addio applied for a patent on the drug combination. The United States Patent and Trademark Office (PTO) examined the application and on July 9, 2002, issued U.S. Patent No. 6,417,206 ("the '206 patent"), which guarantees MedPointe the exclusive right to sell the drug combination.

In Fall 2002, MedPointe launched two commercial products covered by the '206 patent: Tussi-12D tablets and Tussi-12D S suspension. Through October 2003, the combined sales of Tussi-12D products were approximately $15.5 million, with over $11 million attributable to Tussi-12D S. App. 72a. Those products anchor MedPointe's cough/cold business, accounting for approximately 50% of its cough/cold business and much of its total business. In

short, MedPointe's ability to stay in the cough/cold business depends on the performance of its Tussi-12D products.

In Spring 2003, respondent Hi-Tech learned of MedPointe's patented Tussi-12D products, and began developing a copy. App. 21a. Hi-Tech spent only $5,000 to test its copied product, and has conceded that its product would infringe MedPointe's patent if that patent is valid. App. 76a. On the eve of the 2003-2004 cough/cold season, Hi-Tech began offering to sell its copied product, representing it as a substitute for MedPointe's Tussi-12D products by linking it to MedPointe's patented products in nationwide pharmacy databases that identify generic versions of branded drugs.

B. MedPointe's Irreparable Harm.

Hi-Tech's linkage had potentially devastating effects on MedPointe because state laws and insurance plans often require pharmacists to substitute listed generic products for branded products. App. 19a. Once a drug becomes "genericized" in this way, the market cannot revert to its former condition. As is generally true for brand-name drug companies, each time generic substitutes enter the market, MedPointe's sales have plummeted, effectively destroying the markets MedPointe created. For example, when Hi-Tech genericized MedPointe's Tussi-12 reformulated suspension product, MedPointe's sales dropped by eighty percent. They have never recovered.

Those losses affect a significant portion of the company's revenues, and have the potential to result in significant job losses. MedPointe also stands to lose research and development funding for its future products.

C. The District Court Proceedings.

When MedPointe learned that Hi-Tech had linked its copied product to MedPointe's Tussi-12D S in the pharmacy databases, it immediately filed suit seeking a temporary restraining order and a preliminary injunction. App. 84a.

On December 1, 2003, the district court issued a temporary restraining order. The district court conducted a three-day evidentiary hearing on December 22-24, 2003.

Hi-Tech did not contest its infringement of MedPointe's patent at the preliminary injunction hearing. Instead, Hi-Tech argued that MedPointe's patent was invalid as obvious because several other tannate cough/cold products existed before MedPointe's patent was filed, most of which had already been examined by the Patent and Trademark Office.

In the district court, several witnesses testified that the active ingredients used in the previous cough/cold products were of different classes and had both different characteristics and properties than those claimed by MedPointe's patent. Several witnesses further testified about the difficulty of working with tannate salts and that it would ***not*** have been obvious for others to come up with the new patented drug combination in light of the old cough/cold products. App. 65a-66a.

On March 1, 2004, the district court issued a 94-page memorandum opinion, stating its findings of fact, and preliminarily enjoining Hi-Tech pending a trial on the merits. App. 13a-89a. The district court concluded, *inter alia*, that MedPointe had made a "strong showing" of likelihood of success on the merits, and that Hi-Tech had raised no substantial question of invalidity. The district court also recognized that because of MedPointe's large investment in developing Tussi-12D, the company's "continued viability is at stake," and therefore the balance of hardships weighs in MedPointe's favor. App. 87a-88a.

D. The Federal Circuit Proceedings.

On November 17, 2004, a divided panel of the Federal Circuit vacated the preliminary injunction. App. 1a-11a. The majority's decision was based solely on its determination that MedPointe had failed to present a "clear case" that its patent was valid. App. 8a-9a. Chief Judge

Mayer dissented. As an initial matter, Chief Judge Mayer believed that the majority was wrong with respect to this particular case. Pointing to the district court's lengthy consideration of the factual issues, Judge Mayer disagreed with what were essentially three key appellate findings of fact made by the majority: (1) that ammonium chloride was not an active ingredient in the Candettes reference, (2) that tannates are not difficult to work with, and (3) that the commercial success of MedPointe's Tussi-12D product was tenuous. App. 9a-11a.

More significantly, however, Chief Judge Mayer criticized the majority's entire approach toward preliminary injunction review. A preliminary injunction is "to maintain the *status quo* pending a resolution" of the case. App. 9a (Mayer, C.J., dissenting). Judge Mayer described the majority's approach as "*de novo* review of the district court's finding of fact." App. 9a-11a (Mayer, C.J., dissenting). Such a "foray into the virtually exclusive province of the district court has been regularly and consistently criticized by both the Supreme Court and this court." App. 10a.

Panel rehearing was denied on December 17, 2004, along with petitioner's motion to stay issuance of the mandate pending the filing of this petition. App. 12a.

REASONS FOR GRANTING THE WRIT

I. THE FEDERAL CIRCUIT ERRED BY RAISING THE BAR ON PATENTEES SEEKING TO OBTAIN A PRELIMINARY INJUNCTION.

As this Court recognized in *Cardinal Chemical Co. v. Morton International Inc.*, 508 U.S. 83, 89 (1993), the Federal Circuit's "exclusive jurisdiction over appeals from all United States District Courts in patent litigation" makes the rules it applies in patent cases "a matter of special importance to the entire nation." Here, as in *Cardinal Chemical*, the Federal Circuit has adopted a novel rule that

undercuts the value of patents and is inconsistent with the rights granted and the presumptions accorded under the Patent Act. This Court's review is therefore warranted.

A. The Federal Circuit's Preliminary Injunction Requirement Of A "Clear Case" Supporting Patent Validity Is Contrary to Law.

The Federal Circuit in *Amazon.com* decided that a patentee seeking a preliminary injunction must demonstrate, not merely some likelihood of success, but "a clear case supporting the validity of the patent in suit." 239 F.3d at 1359. As the Court of Appeals described its doctrinal modification, "[s]uch a case might be supported, for example, by showing that the patent in suit had successfully withstood previous validity challenges in other proceedings," or that there had been "a long period of industry acquiescence in the patent's validity." *Id.*

A patentee with a new patent, like MedPointe, obviously cannot satisfy that standard by pointing to past litigation or a "long period" of industry practice. The Federal Circuit's review of patent invalidity allows defendants to defeat any preliminary injunction simply by showing that the patent is "vulnerable" to an attack on validity. *See* James Landis, Note, *Amazon.Com: a Look at Patenting Computer Implemented Business Methods Following State Street*, 2 N.C.J.L. & Tech. 1, 15 (2001) ("Very quickly the [Federal Circuit's preliminary] injunction test transforms from balancing to threshold, disregards the presumption of irreparable harm, and shifts and increases the burden of proof to the holder of an officially obtained patent.").

The Federal Circuit's preliminary injunction analysis effectively reverses the burden of proving patent invalidity. Patents are subject to scrutiny before the PTO and are therefore entitled to a presumption of validity. 35 U.S.C. § 282. Consequently, it is the defendant—not the patent holder—who must prove the patent invalid by clear and

convincing evidence. *See Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 810 (1986) (per curiam). The Federal Circuit's preliminary injunction requirement of a "clear case" of patent validity significantly, and unfairly, discounts the presumptive validity of the patentee's right to exclude, particularly where, as here, there is no dispute that the patent is infringed.

The Federal Circuit's approach also deviates from traditional requirements for a preliminary injunction. "The Court has repeatedly held that the basis for injunctive relief in the federal courts has always been irreparable injury and the inadequacy of legal remedies." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982); *see also Amoco*, 480 U.S. at 542. Some likelihood of success on the merits is also required. *See Doran v. Salem Inn, Inc.*, 422 U.S. 922, 931 (1975) ("The traditional standard for granting a preliminary injunction requires the plaintiff to show that in the absence of its issuance he will suffer irreparable injury and also that he is likely to prevail on the merits."). By requiring a patentee to demonstrate a "clear case" of patent validity, however, the Federal Circuit is imposing a non-traditional, heightened showing on the merits, on an issue for which the patentee does not have the burden of proof. Such a new requirement is improper because Congress has not, by a "clear and valid legislative demand," cast aside the "the great principles of equity." *See Weinberger*, 456 U.S. at 313 (quotations omitted). Indeed, Congress expressly directed that injunctive relief in this context adhere to "the principles of equity." 35 U.S.C. § 283.

B. The Injunction Granted By The District Court Satisfied Traditional Equitable Standards.

In this case, the District Court, after a three-day hearing, not only found the patent likely to be valid, but also found that all the other equitable factors supported the issuance of the preliminary injunction. Petitioner presented significant

evidence of irreparable harm without the injunction, including significant and irretrievable loss of market share, job losses, and loss of research and development funding. This evidence was unrebutted, and the district court made findings of fact as to petitioner's significant irreparable harm. App. 81a-89a.

For example, the District Court found "especially credible" the fact that MedPointe would face financial ruin if Tussi-12D is "genericized." App. 87a. As the district court found, "[w]ere genericization to take place, MedPointe's continued viability would be questionable." App. 87a. At a minimum, the district court found that "MedPointe's goodwill would suffer, as would its ability to support and market Tussi-12D by educating physicians in its use." App. 87a. The evidence established that the harm to MedPointe was incalculable, because, as the Federal Circuit has recognized in other cases, a court cannot easily restore a patent holder to the place it held in the market prior to the infringing sales. *See Polymer Tech., Inc. v. Bridwell*, 103 F.3d 970, 976 (Fed. Cir. 1996). An order simply removing the infringing products from the marketplace may not be effective because customers may have established relationships with infringers or turned towards other products. *See id.* All of this evidence of irreparable harm was presented separate and apart from the presumption of irreparable harm that automatically attaches in patent cases.

The Federal Circuit also failed to balance the relative harms and consider the preservation of the *status quo* in this case. The preliminary injunctive relief in this case sought solely to maintain the *status quo*—where the respondent had not yet entered the market and had not yet irreparably harmed MedPointe's market share and goodwill. Chief Judge Mayer aptly noted in his dissent that he would affirm the preliminary injunction "to maintain the *status quo*" pending resolution of the case. App. 9a (Mayer, C.J., dissenting).

C. The Federal Circuit's Aggressive Application Of The "Clear Case" Of Patent Validity Requirement Was The Basis For Vacating The Preliminary Injunction.

The Federal Circuit's heightened standard was outcome-dispositive to this case. The Federal Circuit vacated the preliminary injunction here because it found that MedPointe's patent was "'vulnerable' to attack based on validity," App. 4a, even while conceding that the decision "in no way resolves the ultimate question of invalidity," App. 8a n.5. In fact, as Chief Judge Mayer recognized in dissent, the majority's conclusion about "vulnerability" was based primarily on its disagreement with the district court's factual finding based on the testimony of one witness. App. 9a-11a (Mayer, C.J., dissenting). "The district court, which has special expertise in making credibility determinations, was entitled to disregard [the witness's] testimony, especially in light of [a particular] reference" listed in the patent application." App. 9a-10a. Given that the panel's opinion turned on a narrow disagreement over the evidence before the district court, it is exceedingly likely that had the Federal Circuit applied the appropriate standard, it would have affirmed the issuance of the preliminary injunction.

This case therefore provides a perfect vehicle through which this Court may correct the Federal Circuit's improperly heightened standard for a preliminary injunction in patent cases.

II. REVIEWING PRELIMINARY INJUNCTIONS SOLELY FOCUSING UPON A HEIGHTENED STANDARD ON THE MERITS IS INCONSISTENT WITH THIS COURT'S PRECEDENT AND THE APPROACHES OF OTHER CIRCUITS.

Since its earliest days, the purpose of the preliminary injunction has been to prevent irreparable injury and "to preserve the relative positions of the parties until a trial on

the merits can be held." *See University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981); *see also Yakus v. United States*, 321 U.S. 414, 440 (1944); *Irwin v. Dixion*, 50 U.S. 10, 29 (1850). This Court's precedent requires weighing the full panoply of traditional equitable considerations in deciding whether to grant injunctive relief. *See, e.g., California v. Am. Stores Co.*, 495 U.S. 271, 281 (1990). The Federal Circuit, however, utilizes its requirement of a "clear case" supporting the validity of the patent to review only the merits issue of validity, dispensing with issues of irreparable injury or relative harm. By cutting the traditional equitable inquiry short, the Federal Circuit unduly restricts the availability of the preliminary injunction from the rightful equitable remedies available to plaintiffs in patent cases.

Under traditional standards, the degree of likelihood of success "must be considered and balanced with the comparative injuries of the parties," often described as a "sliding scale" between the factors. *See* 11A Charles Alan Wright, *et al.*, Federal Practice & Procedure § 2948.3, at 189-195 (2d ed. 1995). The Federal Circuit's practice conflicts with the balancing analyses deployed by other circuits. This Court has yet to articulate a detailed standard for granting a preliminary injunction or for appellate review, and considerable divergence has developed in the circuits.

A. The Circuits Apply Conflicting Preliminary Injunction Standards.

Judges and academics have long recognized a circuit split on the standards for determining issuance of a preliminary injunction. *See, e.g.*, Hon. Morton Denlow, *The Motion for a Preliminary Injunction: Time for a Uniform Federal Standard*, 22 Rev. Litig. 495, 497 (2003) (citing John Leubsdorf, *The Standard for Preliminary Injunctions*, 91 Harv. L. Rev. 525, 526 (1978)); Thomas R. Lee,

Preliminary Injunctions and the Status Quo, 58 Wash. & Lee L. Rev. 109 (2001).

The various courts of appeals have developed an assortment of standards in granting a preliminary injunction. Most circuits apply some version of the traditional inquiry and weigh the following factors: (1) whether the plaintiff has an adequate remedy at law, (2) whether the plaintiff will suffer irreparable harm without an injunction, (3) a balancing of the plaintiff's and defendant's harm, (4) whether the plaintiff has a reasonable likelihood of success on the merits, (5) how the injunction will affect the public interest, and (6) the preservation of the *status quo* pending trial on the merits.

For example, the Eighth Circuit considers and balances each factor, but does not require any factor as a threshold. *E.g. United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1178-79 (8th Cir. 1998) (asserting that no single factor is determinative); *see also Ciena Corp. v. Jarrard*, 203 F.3d 312, 322 (4th Cir. 2000); *Déjà Vu of Nashville, Inc. v. Metro. Gov't of Nashville & Davidson County*, 274 F.3d 377, 400 (6th Cir. 2001). Similarly, the D.C. Circuit and the Seventh Circuit balance the factors using a "sliding scale" where "strong" arguments for one factor may support issuance of an injunction despite "weak" arguments in other areas. *E.g.*, *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1318 (D.C. Cir. 1998); *Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 12 (7th Cir. 1992).

Some circuits do not require the movant to establish a "likelihood of success on the merits," but instead allow a preliminary injunction to issue if a plaintiff shows that there are "questions going to the merits ... so serious, substantial, difficult, and doubtful as to make the issue ripe for litigation and deserving of more deliberate investigation." *E.g. Prairie Band of Potawatomi Indians v. Pierce*, 253 F.3d 1234, 1246-47 (10th Cir. 2001) (internal quotation and citation omitted).

Other circuits have instituted different burdens and threshold requirements that must be met before other equitable factors are considered. For example, the Eleventh Circuit requires the movant to establish a "burden of persuasion" as to each of the factors. *E.g. Horton v. City of St. Augustine*, 272 F.3d 1318, 1326 (11th Cir. 2001). The Fifth Circuit requires a threshold showing of "likelihood of success on the merits" before considering other factors. *E.g. Walgreen Co. v. Hood*, 275 F.3d 475, 477-78 (5th Cir. 2001).

Different circuits also consider the various equitable factors in different manners. For example, as to irreparable harm, the Fifth and Eleventh Circuits require a showing of a "substantial threat" of harm. *E.g. Palmer v. Braun*, 287 F.3d 1325, 1329 (11th Cir. 2002). The Tenth and D.C. Circuits require a showing of "substantial likelihood" of success on the merits. *E.g. Kikumura v. Hurley*, 242 F.3d 950, 955 (10th Cir. 2001); *Al-Fayed v. CIA*, 254 F.3d 300, 303 (D.C. Cir. 2001); *Walgreen*, 275 F.3d at 477. The Fourth and Sixth Circuits require only a "likelihood" of success. *E.g. Safety-Kleen, Inc. v. Wyche*, 274 F.3d 846, 858-59 (4th Cir. 2001); *County Sec. Agency v. Ohio Dep't of Commerce*, 296 F.3d 477, 485 (6th Cir. 2002). And other circuits require a "probability" of success on the merits. *E.g. Entergy, Ark., Inc. v. Nebraska*, 210 F.3d 887, 898 (8th Cir. 2000).

Other circuits have adopted two-part balancing tests that incorporate most of the equitable factors. The Second Circuit requires an alternative showing of (1) irreparable harm, and (2) either a likelihood of success on the merits or sufficiently serious questions going to the merits to make them a fair ground for litigation, in addition to a balance of hardships that tips decidedly toward the movant. *E.g. Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc.*, 596 F.2d 70, 72 (2d Cir. 1979) (per curiam). The Ninth Circuit requires either "(1) a combination of probable success on the merits and the possibility of irreparable harm; or (2) that serious questions are raised and the balance of hardships tips in its

favor." *E.g. Sammartano v. First Judicial District Court*, 303 F.3d 959, 965 (9th Cir. 2002) (internal quotation and citation omitted).

B. The Federal Circuit's Fixation Upon Whether A "Clear Case" Of Validity Has Been Shown Is Improper.

The different standards used throughout the various circuits have created confusion throughout the judiciary. Some clarity is possible if the Court were to hold that the Federal Circuit cannot transform appellate review of preliminary injunctions into a mini-trial on a single merits question. Requiring plaintiffs to present a "clear case" of patent validity, *Amazon.Com*, 239 F.3d at 1359, and then focusing appellate review entirely upon that question to the exclusion of the traditional bases for a preliminary injunction places an unwarranted burden on patent holders seeking to show a likelihood of success on the merits, and undercuts the presumption of validity to which all patents are entitled.

Because the Federal Circuit has exclusive jurisdiction over patent appeals, this novel requirement governs all patent preliminary injunction cases in the United States. Because this error devalues, and continues to devalue, the presumption of validity entitled to all patents, the error should not stand uncorrected. *See Cardinal Chem. Co. v. Morton Int'l Inc.*, 508 U.S. 83, 89 (1993). In reviewing that error, the Court can re-affirm and clarify that a preliminary injunction proceeding and appellate review of that proceeding is not a substitute for trial on the merits.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for writ of *certiorari*.

Respectfully submitted,

ERIC B. WOLFF
Counsel of Record
GREGORY F. CORBETT
STEVEN A. ENGEL
KIRKLAND & ELLIS LLP
655 Fifteenth Street, N.W.
Washington, D.C. 20005

Counsel for Petitioner